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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,783	07/07/2006	Roger Bonnert	06275-474US1 101016-1P US	5616
26164 7590 12/07/2009 FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER CHANDRAKUMAR, NIZAL S	
			ART UNIT 1625	PAPER NUMBER
			NOTIFICATION DATE 12/07/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/551,783	Applicant(s) BONNERT ET AL.	
	Examiner NIZAL S. CHANDRAKUMAR	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :09/25/2009, 7/18/2008, 7/18/2008, 10/05/2005.

DETAILED ACTION

This application is a 371 of PCT/SE04/00535 04/06/2004.

Claim 1-8, 10-20 are in the case.

Election/Restrictions

Responsive to a Restriction Requirement having a notification date of August 28, 2009 ("the RR"), Applicants elect "Group 2, claim(s) 1-8 and 10-20, drawn to compounds, composition and methods of treatment wherein Z is phenyl or naphthyl" (RR, page 2). The election is made without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Objection:

Claims 1-5, 7, 8, 10,-14, 16-18 and 20 are objected to for containing non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating asthma and rhinitis, does not reasonably provide enablement for any and all diseases mediated by the compounds of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

All of the factors have been considered with regard to the claims, with the most relevant factors discussed below:

The nature of the invention is the method of treating a disorder that is modulated by prostaglandin D2 (PGD2).

Ulven et al. (Current Topics in Medicinal Chemistry, 2006, 6, 1427-1444) teaches that much work remains to be done to firmly associate individual prostanoids with specific physiological functions (column A, page 1427). Ulven et al. conclude that the

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development of compounds action on one or both of DP and CRTH2 receptors (PGD2 receptors) represent a novel and highly interesting approach for treatment inflammatory conditions, in particular asthma and allergic diseases. Thus, although the involvement of DP in inflammation is established, the evidence is ambiguous about whether DP activation results in a pro- or anti-inflammatory response, and the role of the receptors appears to be depended on various factors. Further, with regards to CRTH2, the teachings the prior art remain speculative and investigational at this point, according to the teachings of Ly et al. (Expert Opinion Investigational Drugs 1005 14(7), 769-773, page 772 section 3 and section 4).

The disclosure in the specification is limited to activity of the instantly claimed compounds in Ligand Binding assay (i.e., in vitro assay). Given the established pharmacological profile of the marketed drug Ramatroban (an indole compound), in view of the instantly disclosed in vitro activity (specification page 113, last three lines) acknowledgement can be made for enabling disclosure with respect to potential use of the instantly claimed compounds for the treatment of asthma and rhinitis.

As such, the state of the prior art is such that it requires screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an

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area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects of all diseases in which PGD2 is implicated, whether or not the modulation of PGD2 receptors would make a difference in the disease. Hence, in the absence of a showing of a nexus between any and all known diseases and the modulation of PGD2 receptors, one of ordinary skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the role of modulation of PGD2 receptors.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of formula (I) for the treatment of any disease. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of formula (I) in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds of the instant claims, with no assurance of success.

This rejection can be overcome by deleting the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 13-20 (compounds), claims 10-12 (methods of use), provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 22, 24 (compounds), claims 13-18 (methods), of copending Application No. 12167513. Although the conflicting claims are not identical, they are not patentably distinct from each other because corresponding claims in the application are drawn to same subject matter compounds of similar formula and or same intended method of use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 13-20 (compounds), claims 10-12 (methods), provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-29 (compounds), claims 30-32 method, of copending Application No. 12089276. Although the conflicting claims are not identical, they are not patentably distinct from each other because corresponding claims in the application are drawn to same subject matter compounds of similar formula and or same intended method of use.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 13-20 (compounds), claims 10-12 (methods), provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 (compounds), claims 9-11 method, of copending Application No. 11576372. Although the conflicting claims are not identical, they are not patentably distinct from each other because corresponding claims in the application are drawn to same subject matter compounds of similar formula and or same intended method of use.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 13-20 (compounds), claims 10-12 (methods), provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-8, 13, 14, 16-18 (compounds), claims 12, 19 method, of copending Application No. 10552082. Although the conflicting claims are not identical, they are not patentably distinct from each other because corresponding claims in the application are drawn to same subject matter compounds of similar formula and or same intended method of use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

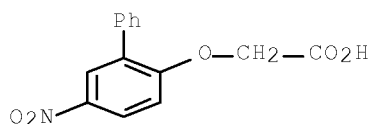
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 13-20 (and claims 10-12 by virtue of dependency) rejected under 35 U.S.C. 102(b) as being anticipated by prior art.

Matsura JP 07140725 teach RN 168094-50-6

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corresponding to compound of the instant formula I wherein

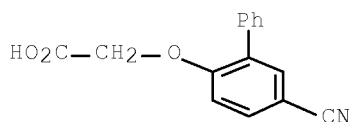
Z is Aryl (phenyl)

R1 = R2 = H

X is nitro

Y is H

Matsura US 5413891 teach RN 163839-76-7



corresponding to compound of the instant formula I wherein

Z is Aryl (phenyl)

R1 = R2 = H

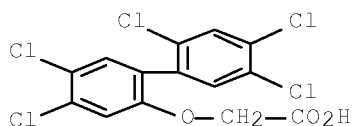
X is cyano

Y is H

Note: Matsura compounds are found in claim 8, numbered page
7/16, lines 3 and 4.

Mattingly US 5145790 teach RN 138588-74-6

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corresponding to compound of the instant formula I wherein

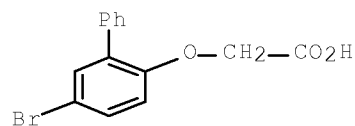
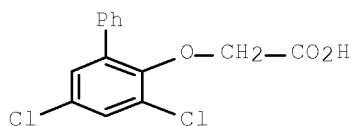
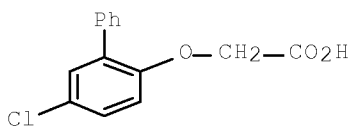
Z is Aryl (phenyl substituted with halogens)

R1 = R2 = H

X is halogen (chlorine)

Y is halogen (chlorine)

Dalal et al. Journal of the Indian Chemical Society (1949), 26, 549-52



RN 20292-25-5

RN 20292-26-6

RN 500308-30-5

corresponding to compound of the instant formula I wherein

Z is Aryl (phenyl substituted with halogens)

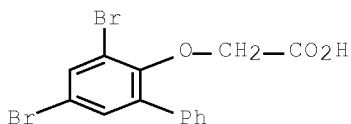
R1 = R2 = H

X is halogen (chlorine for the first two structures, bromine for the second structure)

Y is hydrogen for the first and third structure), halogen (chlorine for the second structure)

Hazlet et al. Journal of the American Chemical Society (1941), 63, 1890-2.

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RN 860540-97-2

corresponding to compound of the instant formula I wherein

Z is Aryl (phenyl substituted with halogens)

R1 = R2 = H

X is halogen (bromine)

Y is halogen (bromine)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nizal S Chandrakumar/
Examiner, Art Unit 1625

/D. Margaret Seaman/
Primary Examiner, Art Unit 1625